

**Listing of Claims:**

This listing of claims will replace all prior versions and listings of claims in the application:

1. (Currently Amended) A method of making a stabilized hydrogen peroxide composition comprising ~~greater than 0 to about 2% wt. % or less 2 wt. %~~ of hydrogen peroxide, based on the total weight of the composition, which is suitable for application to human skin, the method comprising:
  - (a) adding to water about 0.05 to about 0.5 wt. % of polycarboxylic acid having a chain length of 2 to 6 carbon atoms, a tin salt in an amount of about 0.005 to about 0.05 wt. % based on weight of tin, about 0.02 to about 0.5 wt. % of salicylic acid or a salt of salicylic acid, and about 1 to about 35 wt. % of at least one monoglyceride of a fatty acid having a carbon chain length of ~~12 to 16~~ 10 to 16 carbon atoms in crystalline form to form a solution, wherein all wt. % are based on the total weight of the composition;
  - (b) heating ~~said the solution of step (a)~~ to a temperature sufficient to melt said crystalline monoglyceride;
  - (c) cooling said solution at a controlled rate to form crystals; and
  - (d) adjusting the pH to about 3.5 to about 4.9.
2. (Currently amended) ~~The~~ [A] method according to claim 1, wherein said solution is heated to a temperature of about 70°C to dissolve said crystalline monglyceride.
3. (Currently amended) ~~The~~ [A] method according to claim 1, wherein said solution is cooled at a rate of about 0.1 to about 10°C per minute.
4. (Currently amended) ~~The~~ [A] method according to claim 3, wherein said solution is cooled at a fixed rate.
5. (Currently amended) ~~The~~ [A] method according to claim 1, wherein said polycarboxylic acid is added in amount of about 0.1 to about 0.3 wt. %; said tin salt is added in

an amount of about 0.01 to about 0.03 wt. % [by], based on the weight of tin; and said salicylic acid is added in an amount of about 0.05 to about 0.2 wt. %.

6. (Currently amended) The [A] method according to claim 1, wherein said pH is adjusted to be from about 4.75 to about 4.9.

7. (Currently amended) The [A] method according to claim 1, wherein said crystalline monoglyceride comprises 1-Glycerolmonolaurate, ~~C12 (C12)~~, and 1-Glycerolmonomyristate, ~~C14 (C14)~~.

8. (Currently amended) The [A] method according to claim 7, wherein the amount of and the ratio between C12 and C14 are varied depending on the desired viscosity of the composition.

9. (Currently amended) The [A] method according to claim 7, wherein the ratio C12 : C14 is from 1:3 to 1:1 for a cream product and from 1:3 to 1:0 for a lotion or spray form product with lower viscosity.

10. (Currently amended) The [A] method according to claim 1, wherein the amount of crystalline monoglycerides is from about 15 to about 35 wt. % when a cream product is desired.

11. (Currently amended) The [A] method according to claim 1, wherein the amount of crystalline monoglycerides from about 1 to about 15 wt. % when a lotion or spray product is desired.

12. (Currently amended) The [A] method according to claim 1, wherein said polycarboxylic acid comprises oxalic acid.

13. (Currently amended) The [A] method according to claim 1, further comprising adding a buffer to said solution.

14. (Currently amended)      ~~The~~ [A] method according to claim 13, wherein said buffer comprises at least one ~~buffer~~ selected from the group consisting of phosphate buffers and citrate buffers.
15. (Currently amended)      ~~The~~ [A] method according to claim 1, further comprising adding [a] ~~at least one~~ stabilizer ~~comprising at least one~~ selected from the group consisting of pyrophosphate and sequestrants.
16. (Currently amended)      ~~The~~ [A] method according to claim 15, wherein said ~~at least one~~ stabilizer comprises EDTA or phosphonic acid.
17. (Currently amended)      ~~The~~ [A] method according to claim 1, further comprising adding a physical ~~stabilisers~~ stabilizer against sedimentation of the lipids.
18. (Currently amended)      ~~The~~ [A] method according to claim 17, wherein said physical stabilizer comprises a polar surfactant having an HLB over 20.
19. (Currently amended)      ~~The~~ [A] method according to claim 17, wherein said physical stabilizer comprises a thickener.
20. (Currently amended)      ~~The~~ [A] method according to claim 19, wherein said thickener comprises a polyacrylic acid ~~derivatives~~ derivative.
21. (Currently amended)      ~~The~~ [A] method according to claim 1, further comprising adding a dermatological agent.
22. (Currently amended)      ~~The~~ [A] method according to claim 21, wherein said dermatological agent comprises glycerol or propyleneglycol.
23. (Currently amended)      ~~The~~ [A] method according to claim 1, wherein said composition retains a hydrogen peroxide efficacy of at least 90% after 2 years.
24. (Currently amended)      ~~The~~ [A] method according to claim 1, wherein said

crystalline monoglyceride has a carbon chain length of from about 10 to about 14.

25. (Currently amended) A method of making a stabilized hydrogen peroxide composition comprising ~~greater than 0 to~~ about [2%] 2 wt. % ~~or less~~ of hydrogen peroxide, based on the total weight of the composition, which is suitable for application to human skin, the method comprising:

- (a) adding to water a polycarboxylic acid having a chain length of 2 to 6 carbon atoms, a tin salt, salicylic acid or a salt of salicylic acid, and at least one monoglyceride of a fatty acid in crystalline form to form a mixture;
- (b) heating said ~~solution mixture of step (a)~~ to a temperature sufficient to melt said crystalline monoglyceride;
- (c) cooling said ~~solution mixture~~ at a controlled rate to form crystals; and
- (d) adjusting the pH to about 3.5 to about 4.9.

26. (Currently amended) A pharmaceutical, hydrogen peroxide composition which is suitable for application to human skin, comprising:

- (i) ~~greater than 0 to~~ about 2 wt. % ~~or less~~ of hydrogen peroxide;
- (ii) about 0.05 to about 0.5 wt. % of polycarboxylic acid having a chain length of 2 to 6 carbon atoms;
- (iii) a tin salt in an amount of about 0.005 to about 0.05 ~~wt %~~ wt. %, based on weight of tin;
- (iv) about 0.02 to about 0.5 wt. % of salicylic acid or a salt of salicylic acid;
- (v) about 1 to about 35 wt. % of at least one monoglyceride of a fatty acid in crystalline form, ~~to form a mixture~~; and balance water, in admixture,

wherein said composition has a pH of about 3.5 to about 4.9, and wherein all wt. % are based on the total weight of the composition.

27. (Currently amended) The [A] composition according to claim 26, wherein said polycarboxylic acid is present in amount of about 0.1 to about 0.3 wt. %; said tin salt is present in

an amount of about 0.01 to about 0.03 wt. % based on the weight of tin; and said salicylic acid is present in an amount of about 0.05 to about 0.2 wt. %.

28. (Currently amended) The [A] composition according to claim 26, wherein said pH is from about 4.5 to about 4.9.

29. (Currently amended) The [A] composition according to claim 26, wherein said crystalline monoglyceride comprises 1-Glycerolmonolaurate, ~~C12 (C12)~~, and 1-Glycerolmonomyristate, ~~C14 (C14)~~.

30. (Currently amended) The [A] composition according to claim 29, wherein the amount of and the ratio between C12 and C14 depends on the desired viscosity of the composition.

31. (Currently amended) The [A] composition according to claim 29, wherein the ratio C12:C14 is from 1:3 to 1:1 for a cream product and from 1:3 to 1:0 for a lotion or spray form product with lower viscosity.

32. (Currently amended) The [A] composition according to claim 26, wherein the amount of crystalline monoglycerides is from about 15 to about 35 wt. %.

33. (Currently amended) The [A] composition according to claim 26, wherein the amount of crystalline monoglycerides from about 1 to about 15 wt. %.

34. (Currently amended) The [A] composition according to claim 26, wherein said polycarboxylic acid comprises oxalic acid.

35. (Currently amended) The [A] composition according to claim 26, further comprising a buffer.

36. (Currently amended) The [A] composition according to claim 35, wherein said buffer comprises at least one buffer selected from the group consisting of phosphate buffers and

citrate buffers.

37. (Currently amended) The [A] composition according to claim 26, further comprising at least one [a] stabilizer selected from the group consisting of pyrophosphate and sequestrants.

38. (Currently amended) The [A] composition according to claim 37, wherein said at least one stabilizer comprises EDTA or phosphonic acid.

39. (Currently amended) The [A] composition according to claim 26, further comprising a physical ~~stabilizers~~ stabilizer against sedimentation of the lipids.

40. (Currently amended) The [A] composition according to claim 39, wherein said physical stabilizer comprises a polar surfactant having an HLB over 20.

41. (Currently amended) The [A] composition according to claim 39, wherein said physical stabilizer comprises a thickener.

42. (Currently amended) The [A] composition according to claim 41, wherein said thickener comprises a polyacrylic acid ~~derivatives~~ derivative.

43. (Currently amended) The [A] composition according to claim 26, further comprising a dermatological agent.

44. (Currently amended) The [A] composition according to claim 43, wherein said dermatological agent comprises glycerol or propyleneglycol.

45. (Currently amended) The [A] composition according to claim 26, wherein said composition retains a hydrogen peroxide efficacy of at least 90% after 2 years.

46. (Currently amended) The [A] composition according to claim 26, wherein said crystalline monoglyceride has a carbon chain length of from about 12 to about 16 carbon atoms.

Inventor: Ake R. LINDAHL  
U.S. Serial No.: 09/891,256  
Filing Date: June 27, 2001

Attorney Docket No.: 28069-531  
(Formerly: 62-262)

47. (Currently amended) A pharmaceutical, hydrogen peroxide composition which is suitable for application to human skin comprising:

- (i) ~~greater than 0 to~~ about 2 wt. % ~~or less~~ of hydrogen peroxide;
- (ii) a polycarboxylic acid having a chain length of 2 to 6 carbon atoms;
- (iii) a tin salt;
- (iv) salicylic acid or a salt of salicylic acid;
- (v) at least one monoglyceride of a fatty acid in crystalline form, ~~to form a mixture;~~  
and balance water, ~~in admixture,~~

wherein said composition has a pH of about 3.5 to about 4.9, and wherein all wt. % are based on the total weight of the composition.